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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/540,609	06/27/2005	Akihide Mori	550718-112	9184

27805 7590 01/28/2008  
THOMPSON HINE L.L.P.  
Intellectual Property Group  
P.O. BOX 8801  
DAYTON, OH 45401-8801

EXAMINER
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HALL, DEANNA K

ART UNIT	PAPER NUMBER
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3767

MAIL DATE	DELIVERY MODE
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01/28/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

**Office Action Summary**

Application No.

10/540,609

Applicant(s)

MORI ET AL.

Examiner

Deanna K. Hall

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 02 January 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1, 2 and 5-6 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 2 and 5-6 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on June 27, 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### *Acknowledgments*

1. This office action is in response to the reply filed on January 2, 2008.
2. Applicant's argument regarding the limitations of claim 7 are persuasive; however, the examiner wishes to add new art to change the previous final rejection. Because applicant amended the claims, examiner may change the rejection and make the action final.
3. In the reply on January 2, 2008, the applicant amended claim 1 and cancelled claims 7-10.
4. Claims 1-2 and 5-6 remain pending in this application.

### *Claim Rejections - 35 USC § 103*

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 1-2 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gray (US 6,830,564) in view of Caselli (US 5,201,710) further in view of Lary (US 4,548,601).

Gray discloses a syringe body 100 including a cylindrical barrel 101 having a needle mounting portion 101RDN on one end and an opening portion 101RO on the other end, and a needle 105 mounted on the needle mounting portion. Restricting means 107 for restricting the movement of the piston so that the cylindrical barrel is prefilled C14 L38-40 with a liquid medicine and then closed by the piston. C15 L18-30.

The piston movement restricting means comprises a bellows 107 and a fixing sheet with the bellows composed of an alternating circumferential portion 107P and trough portion 107W. The bellows cover at least a portion of the piston C18 L63-67 and the fixing sheet is glued onto the circumferential portion of the bellows C15 L25-30.

Gray discloses the invention as substantially claimed (see above). In addition Gray discloses a closing diaphragm 606 having crossing notches inside the opening storage portion and an end cap 611, See Figs. 12 and 13B. An object of Gray's invention is to prevent contamination C1 L5- C2 L51. Gray does not directly disclose retracting the needle into a hollow piston rod. Caselli, in the analogous art, teaches a hollow piston rod 7 with an end cap 8 and an opening storage portion wherein the needle is stored Fig. 9. Therefore it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify the device of Gray with the hollow piston and end cap as taught by Caselli for retracting the needle into the hollow piston for storage to prevent contamination Gray C1 L5- C2 L51.

Further, the combination of Gray/Caselli discloses the invention as substantially claimed but does not directly disclose a liquid-prefilled flexible pouch arranged in the cylindrical barrel, wherein a proximal sharp end of the needle is projected in the

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cylindrical barrel. Lary, in the analogous art, teaches a liquid-prefilled flexible pouch 12 arranged in the cylindrical barrel 11, wherein a proximal sharp end of the needle is projected in the cylindrical barrel, see Fig. 7. Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify the combination of Gray/Caselli with the flexible pouch punctured by the proximal sharp end of the needle as taught by Lary for providing a low-cost disposable injector.

**7. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gray/Caselli/Lary in view of Chen (US 6,616,640).**

The combination of Gray/Caselli/Lary shows as discussed above. An object of Gray's invention is to prevent accidental separation of the plunger from the barrel Gray C2 L37-41. Chen, in the analogous art, teaches a reverse-movement prevention stopper ring 81 in the cylindrical barrel of the syringe body and a number of reverse-movement prevention projections 82 arranged on the piston rod wherein the projections are stopped by the stopper ring C4 L8-24. Therefore it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify the device of Gray/Caselli/Lary with the plunger anti-detachment mechanism 80 as taught by Chen for preventing the accidental separation of the plunger from the barrel Gray C2 L37-41.

**8. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gray/Caselli/Lary in view of Sampson (US 5,098,403).**

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The combination of Gray/Caselli/Lary shows as discussed above. The object of Gray's invention is to prevent contamination C1 L5- C2 L51. Sampson, in the analogous art, teaches a slide cover movable along the barrel of the syringe body Sampson Fig. 2. Therefore it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify the device of Gray/Caselli/Lary with the slide cover Fig. 2 as taught by Sampson for preventing contamination by making the needle retractable Gray C1 L5- C2 L51.

### ***Response to Arguments***

9. Applicant's arguments with respect to the rejection of claim 7 under 35 U.S.C. 103(a) as being unpatentable over Gray and Caselli in view of Sampson (US 5,098,403) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made by combining the Lary (US 4,548,601) reference with Gray and Caselli. Lary teaches a liquid-prefilled flexible pouch 12 arranged in the cylindrical barrel 11, wherein a proximal sharp end of the needle is projected in the cylindrical barrel, see Fig. 7.

### ***Conclusion***

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deanna K. Hall whose telephone number is 571-272-2819. The examiner can normally be reached on M-F 9:00am-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on 571-272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Deanna K. Hall  
Examiner  
AU 3767

dkh

KEVIN C. SIRMONS  
SUPERVISORY PATENT EXAMINER

